correlate well with topics on the syllabi of most traditional medical school courses [3]. In addition, many interactions in the ED are unpredictable, influenced by arbitrary patient assignments, informal encounters, and fortunate (or unfortunate) accidents. Such challenges are further confounded by issues that are common for all EM learners – taking short cuts, acknowledging mistakes, engaging bias, and choosing appropriate role models. Recurring themes included caring and compassion, sensitivity, appropriate use of symptomatic care; and integrity in conduct and responsibility with patients. Students appear to be thoughtfully monitoring their experiences and interactions in order to determine their own desired future behavior. These results are consistent with other investigators who analyzed narratives from fourth-year medical students and concluded that day-to-day clinical experiences in the ED influenced professional development [1,4]. Although our study focused on beginning medical students, similar observations are likely made by residents, novice faculty, and ED staff.

Perhaps the first step to meaningful curricular change is simply to listen to our students. Their descriptions of what they are learning reveal what we are actually teaching [3]. Faculty and residents may not fully be able to see and to hear beliefs, standards, and implicit codes of behavior as they pass these on to the next generation. Future research efforts could address this further by investigating the impact of sharing the results of student reflective essays with residents, faculty and staff.

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References

[1] Bernard AW, Malone M, Kman NE, Caterino JM, Khandelwal S. Medical student professionalism narratives: a thematic analysis and interdisciplinary comparative investigation. BMC Emerg Med 2011;11(8):11–9.
[2] Karnieli-Miller O, Vu TR, Holtman MC, Clyman SG, Inui TS. Medical students' professionalism narratives: a window on the informal and hidden curriculum. Acad Med 2010;85(1):124–33.
[3] Gaufberg EH, Batalden M, Sands R, Bell SK. The hidden curriculum: what can we learn from third-year medical student narrative reflections? Acad Med 2010;85(11):1709–16.
[4] Santeen SA, Hemphill RR. A window on professionalism in the emergency department through medical student narratives. Ann Emerg Med 2011;58(3):288–94.

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Retrospective chart reviews: Assessing delays in IRB approval

The retrospective chart review (RCR), also known as a medical record review, is a commonly used study design in the emergency medicine literature [1,2]. The RCR uses pre-recorded, patient-centered data to answer one or more research questions. Federal regulations require that retrospective chart reviews RCRs be reviewed and approved by a local institutional review board (IRB) prior to conducting the research [3]. IRB approval may be delayed because of missing, incomplete or contradictory documentation, errors, or omissions in the protocol or application. The aim of our study is to review research proposals submitted to the Institutional Review Board (IRB) at one academic medical center to 1) determine the proportion of research protocols that use data exclusively from chart reviews; and 2) assess and quantify the kinds of documentation deficiencies commonly seen.

This was a cross-sectional analysis using research proposals submitted to the IRB at one academic-affiliated medical center during a 54-month study period. Inclusion criteria included any original research proposals that relied solely on data from medical records to answer the questions posed by the study. Exclusion criteria included research proposals relying on death certificates, coroners' reports, or other public records, and all studies based on animal or laboratory investigations. The proportion of all original research protocols that relied on chart reviews and the proportions of chart review articles that qualify for exempt versus expedited review were determined. We quantified the time required from submission to final IRB approval using times recorded by IRBManager software. In addition, IRB communications to the principal investigator were analyzed to determine the reasons for delays in IRB approval. To ensure the accuracy of data abstraction, all investigators assessed several mock research proposals to evaluate the consistency of coding and to clarify the coding system. A blinded critical review of a random sample of 10% of the charts was

Table 1
Deficiencies noted in retrospective protocols submitted to IRB (N = 796).

Logistic (administrative)	
Missing documentation (CITI, COI, other)	128 (16.1%)
Personnel issues/changes	81 (10.2%)
Inadequate rationale for waiver	37 (4.6%)
Version control:	31 (3.9%)
Problems with the application (describe)	19 (2.4%)
Participating institutions (setting)	18 (2.3%)
Other (describe):	8 (1.0%)
Editorial	
Clarifications in the protocol	72 (9.0%)
Definition of variables	26 (3.3%)
Adding or deleting sentences	17 (2.1%)
Word choice, grammar, tense, phrasing	8 (1.0%)
Other (describe):	7 (0.9%)
Procedural	
Data elements (database described)	82 (10.3%)
Sample size calculated	46 (5.8%)
Missing inclusion or exclusion criteria	33 (4.1%)
Timelines	25 (3.1%)
Chart review procedure	17 (2.1%)
Unclear hypothesis or aim	15 (1.9%)
Statistical questions	13 (1.6%)
Inadequate justification	8 (1.0%)
Other (describe):	10 (1.3%)
Ethical	
Data storage	67 (8.4%)
Subject privacy and confidentiality (HIPAA)	19 (2.4%)
Other (describe):	8 (1.0%)

done to determine interrater reliability. The interrater agreement for this sample of charts was determined using kappa statistics. Descriptive statistics (mean, SD) and frequency tables were used to describe the key quantitative and qualitative variables.

During the study period, 563 RCRs were submitted to the IRB; 172 studies were excluded from analysis because they were categorized as non-human subjects research (NHSR) (74%), withdrawn by investigator (21%), or evaluated primarily by another IRB (5%). A total of 391 protocols used a retrospective study design and were included in our analysis. This represented 28.4% of all the eligible protocols submitted during the study period. These retrospective protocols represented 28 medical specialties, including cardiovascular (15%), pediatrics (12%), pharmacy (12%), general surgery (10%), neurosciences (9%) and emergency medicine (7%). Faculty physicians were generally the principal investigators (74%), followed by residents (14%), pharmD (8%), nursing staff (2%) and medical students (2%).

Of the 391 protocols, 43 (11%) were exempt, 348 (89%) were expedited by the IRB. Overall, 233 (59.6%) were sent back to the principal investigators for revisions prior to final approval. A total of 796 deficiencies were documented in RCRs for an average of 2.0 ± 2.7 deficiencies per protocol (Table 1). Common deficiencies included poor documentation, personnel issues, missing data elements, and inadequate description of data storage. IRB turnaround time for those studies that did not need revision (submission to approval) was 26.4 ± 15.1 calendar days. IRB turnaround time for those studies that required revision was 38.6 ± 23.6 days. There was no correlation between total number of revisions and turnaround time in days ($r = 0.188$). Interrater reliability was calculated across the 17 methodologic criteria; the consistency of the data recording was excellent, with a median kappa statistic of 0.88.

In general, investigators should plan to submit a complete application for IRB review at least one month prior to beginning an RCR. Almost 60% of protocols were not approved on the first review because of missing, incomplete or contradictory documentation, errors, or omissions in the protocol or application. IRB staff are available in most institutions answer questions about IRB requests for modifications or clarification and can offer guidance on how to revise submission materials accordingly. Suggestions to potential investigators include: eliminate partial responses to IRB questions, obtain statistical consult prior to submission, have another investigator pre-review submission, update required research training and conflict of interest questionnaires, use IRB templates when possible, and include a description of safeguards to adequately protect retrospective data from a breach of confidentiality.

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References

[1] Babcock D, Kelly A, Kerr D, Reade T. The quality of medical record review studies in the international emergency medicine literature. Ann Emerg Med 2005;45(4):444–7.
[2] Worster A, Haines T. Advanced Statistics: understanding medical record review (MRR) studies. Acad Emerg Med 2004;11(2):187–92.
[3] Fontanesi J, Magit A, Ford JJ, Nguyen H, Firestein GS. Systems approach to assessing and improving local human research Institutional Review Board performance. J Clin Transl Sci 2018;2(1):103–9.

Lemierre's syndrome: A forgotten complication of acute pharyngitis

Lemierre's syndrome (LS) is a rare disease of the head and neck that is often characterized by a history of oropharyngeal infection, leading to septic thrombophlebitis of the internal jugular vein (IJV) and septic lesions in more distant organs, such as the lung [1,2]. Patients diagnosed with LS in the Emergency Department (ED) are generally healthy teenagers and young adults, who present with a history of several days of sore throat accompanied by fever before more severe symptoms begin [3]. LS is difficult to diagnose due to non-specific symptoms, and frequently minimal clinical findings in the neck and oropharynx [3]. Pleural effusions, cavitary pulmonary lesions, and venous thrombosis are common findings on pulmonary imaging [3]. This syndrome is most often a result of a *Fusobacterium necrophorum* infection. *Fusobacterium* spp. are gram negative anaerobes and are part of the normal human microflora of the oropharynx, genitourinary and gastrointestinal tracts [1]. Other pathogens that cause LS include *Streptococcus viridans*, *Bacteroides*, *Peptostreptococcus*, and *Enterococcus* spp. [2]. Prognosis for patients suffering from LS is quite good if given prompt intravenous antibiotic therapy and supportive care. The objective of this study was to assess the incidence, clinical characteristics, and microbiologic source for patients diagnosed with Lemierre's syndrome from three academic medical centers in West Michigan.

We performed a retrospective cohort study using a database of all admissions to three adult and pediatric hospitals in West Michigan during a ten-year study period. Eligible patients presented with both a history of an oropharyngeal infection and internal jugular vein thrombophlebitis with an isolated or mixed *Fusobacterium necrophorum* infection, or an infectious disease specialist diagnosed Lemierre's syndrome. Clinical records were reviewed for demographic data, presenting symptoms, initial vital signs, emergency physician evaluation, and laboratory data. Metastatic complications, hospital length of stay, and mortality were assessed as well.

During the study period, 16 patients with Lemierre's syndrome presented to one of the participating hospitals. Nine (56%) subjects were female. The majority (75%) were ≤24 years of age (range 12–76). The average duration of symptoms prior to hospital admission was 7 days (range 2–14). A typical presentation was a significant increase in fever (39–41 °C), often associated with rigors, approximately 5 days after the onset of a sore throat. Other clinical features included a history of fever 15 (94%), pharyngitis or tonsillitis 15 (94%), cervical adenopathy 12 (75%), lateral neck pain or swelling 11 (69%), myalgia/arthralgias 11 (69%), rigors 9 (56%), leukocytosis (>15K) 5 (31%), and dyspnea or cough 4 (25%). The diagnosis was generally made by a cervical or thoracic CT with contrast (50%), ultrasound (44%), or MRI (6%). The microbiologic source for these infections included *Fusobacterium* (50%), MRSA (16%), anaerobic *Streptococcus* (6%), and *Bacteroides* (6%).

All patients were given anticoagulation for septic emboli, broad spectrum IV antibiotic coverage (7–15 days), and surgery for abscess drainage (31%). Infectious complications included pulmonary (emboli, effusion) 10 (63%), elevated liver enzymes 9 (56%), liver/splenic abscesses 4 (19%), septic arthritis 3 (19%), septic shock 3 (19%), cutaneous abscess 2 (13%), and renal failure 2 (13%). All patients survived and the average length of hospitalization was 11.8 days (range 7–32).

Recent data suggest that in adolescents and young adults (persons aged 15 to 30 years), *Fusobacterium necrophorum* causes